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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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AGENSYS C/O MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE, SUITE 500
SAN DIEGO, CA 92130

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,312	JAKOBOVITS ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 39 in part, as specifically drawn to a polynucleotide that encodes an 84P2A9-related protein, classified in class 536, subclass 23.5.

(Upon election of Group I, the applicant must choose ONE supermotif from those listed in Claim 13 and ONE polypeptide for which the nucleic acid encodes listed in Claim 4, as each supermotif and polypeptide is a distinct invention requiring separate searches, NOT a species)

II. Claims 11-15 and 39 in part, as specifically drawn to an isolated 84P2A9-related protein, classified in class 530, subclass 350.

(Upon election of Group II, the applicant must choose ONE SEQ ID amino acid SEQ ID NO from those listed in the specification, as each SEQ ID NO is a distinct invention, NOT a species)

III. Claims 16-23, 25-26 and 39 in part, as specifically drawn to an antibody, classified in class 530, subclass 388.1.

(Upon election of Group III, the applicant must choose ONE SEQ ID amino acid SEQ ID NO from those listed in the specification, as each SEQ ID NO is a distinct invention, NOT a species)

IV. Claim 24, as specifically drawn to a non-human transgenic animal, classified in class 800, subclass 13.

V. Claim 27 and 39 in part, as specifically drawn to a vector comprising a polynucleotide encoding a monoclonal antibody that immunospecifically binds to an 84P2A9-related protein, classified in class 435, subclass 320.1.

VI. Claims 28-29, 30-33 and 35-36, as specifically drawn to an assay for detecting the presence of an 84P2A9-related polynucleotide, classified in class 435, subclass 6.

VII. Claims 28-29, 32, 34-36, as specifically drawn to an assay for detecting the presence of an 84P2A9-related polypeptide, classified in class 435, subclass 7.1.

VIII. Claims 37-38, as specifically drawn to the use an 84P2A9-related "agent" for the preparation of a composition for treating a patient with a cancer that expresses 84P2A9, classified in class 434, subclass 9.2.
(**Upon election of Group VIII, the applicant must choose ONE "agent" from those listed in Claim 37, as each "agent" is a distinct invention requiring separate searches, NOT a species. Note: the term agent is a generic term representing, a protein, a vector, an antisense, or a ribozyme**)

IX. Claim 40, as specifically drawn to a method of treating a patient with a cancer that express 84P2A9 which comprising administering a vector comprising a polynucleotide encoding a single chain monoclonal antibody, classified in class 514, subclass 44.

X. Claim 41, as specifically drawn to a vaccine composition for the treatment of a cancer expressing 84P2A9 comprising an immunogenic portion of an 84P2A9-related protein, classified in class 514, subclass 2.

XI. Claim 42-43, as specifically drawn to a method of inhibiting the development of a cancer expressing 84P2A9 in a patient, comprising administering to a patient an effective amount of a vaccine composition, classified in class 424, subclass 184.1.

XII. Claim 44, as specifically drawn to a method of delivering a cytotoxic agent to a cell expressing 84P2A9, classified in class 424, subclass 181.1.

XIII. Claims 45-46, as specifically drawn to a method of inducing an immune response to an 84P2A9 protein by contacting an epitope with an immune system cell, wherein the immune system cell is a B cell, classified in class 435, subclass 7.24.

XIV. Claims 45 and 47, as specifically drawn to a method of inducing an immune response to an 84P2A9 protein by contacting an epitope with an immune system cell, wherein the immune system cell is a cytotoxic T cell, classified in class 435, subclass 7.24.

XV. Claims 45 and 48, as specifically drawn to a method of inducing an immune response to an 84P2A9 protein by contacting an epitope with an immune system cell, wherein the immune system cell is a helper T cell, classified in class 435, subclass 7.24.

The inventions are distinct, each from the other because of the following reasons:

The invention of Group I is related to the invention of Group II by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is a search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest

there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides with modified amino acids of the amino acid sequences identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of Groups I and II.

The antibody of Group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such as the antibody of Group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group I and Group III would impose a serious search burden since a search of the polynucleotide of Group I would not be used to determine the patentability of an antibody of Group III, and vice-versa.

The invention of Group I and the invention of Group V are related by virtue of the fact that the vector comprises a polynucleotide encoding a monoclonal antibody. In the instant case, the search of the polynucleotide and vector are not coextensive. The vector has utility to transfer a DNA sequence from one organism to another. Although the vector and the polynucleotide are related, since the vector comprises a polynucleotide encoding a monoclonal antibody , they are distinct inventions because the polynucleotide can be transferred from one organism to another by other and materially distinct process, such as electroporation

Furthermore, searching the inventions of Groups I and V together would impose a serious search burden. In the instant case, the search of the vector and polynucleotide are not coextensive.

The inventions of Groups I and V have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is a search burden also in the non-patent literature. There may be journal articles devoted solely to polynucleotides which would not have described the vector. Similarly, there may have been "classical" genetics papers which had no knowledge of the vector but spoke to the polynucleotide. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of Groups I and V.

While the inventions of both Group II and Group III are polypeptides, in this instance the polypeptide of Group II is a single chain molecule, whereas the polypeptide of Group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDR) that function to bind an epitope. Thus the polypeptide of Group II and the antibody of Group III are structurally distinct molecules; any relationship between a polypeptide of Group II and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. Therefore, the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of Group II and Group III would impose a serious search burden. The inventions have separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Furthermore, antibodies which bind to an epitope of a polypeptide of Group II may be known even if a polypeptide of Group II is novel. In addition, the technical literature search for the polypeptide of Group II and the antibody of Group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The invention of Group II and the invention of Group X are related by virtue of the fact that the vaccine composition comprises an immunogenic portion of an 84P2A9-related protein. In the instant case, the search of the vaccine and protein are not coextensive. The vaccine composition has utility for the treatment of cancer expressing 84P2A9. Although the vaccine composition and protein are related, since the vaccine comprises the specifically claimed protein for the treatment of cancer, they are distinct inventions because the protein product can be used by other and materially distinct processes, such as for the production of antibodies in a cell.

Furthermore, searching the inventions of Groups II and X together would impose a serious search burden. In the instant case, the search of the polypeptides and vaccine composition are not coextensive. The inventions of Groups II and X have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is a search burden also in the non-patent literature. There may be journal articles devoted solely to proteins which would not have described the vaccine composition. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of Groups II and X.

The inventions of Groups VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that the products would be used together. An assay for detecting the presence of an 84P2A9-related polynucleotide (Group VI) and an assay for detecting the presence of an 84P2A9-related polypeptide (Group VII) are unrelated as they comprise distinct steps and utilize different materials which demonstrates that each product has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for each assay differ significantly for each of the materials. An assay for detecting the nucleic acid, may utilize hybridization. An assay for detecting a polypeptide, may utilize an antibody. Therefore, each product is divergent in materials and methodology. For these reasons the inventions of Groups VI-VII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups VI-VII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups VI-VII.

The invention of Group III and the invention of Group IV are related by virtue of the fact that the non-human transgenic animal produces the antibody. In the instant case, the search of the antibody and non-human transgenic animal are not coextensive. The non-human transgenic animal has utility for the production of the antibody. Although the non-human transgenic animal and the antibody are related, since the non-human transgenic animal produces the specifically claimed antibody, they are distinct inventions because the antibody product can be made by other and materially distinct processes, such as purification from the natural source. Further, a non-human transgenic animal can be used for processes other than the production of antibodies, such as in an in vivo test method.

Furthermore, searching the inventions of Groups III and IV together would impose a serious search burden. In the instant case, the search of the polypeptides and a non-human transgenic animal are not coextensive. The inventions of Groups III and IV have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is a search burden also in the non-patent literature. There may be journal articles devoted solely to antibodies which would not have described the non-human transgenic animal. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of Groups III and IV.

The inventions of Groups VIII-IX and XI-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The use of an 84P2A9-related "agent" for the preparation of a composition (Group VIII), a method for treating a patient with cancer (Group IX), the method of inhibiting the development of a cancer (Group XI), the method of delivering a cytotoxic agent to a cell (Group XII) and the methods of inducing an immune response (Groups XIII-XV) are unrelated as the comprise distinct steps and

utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for the use of an agent, treatment, inhibition, delivering, and inducing an immune response differ significantly for each of the materials. For the use of an agent, any agent such as a small organic compound, peptide, antibody or inorganic compound may be used. For treatment, the vector is administered to a patient having cancer using any mode of administration. For delivering a cytotoxic agent to a cell, any cytotoxic agent may be conjugated to an antibody. For inducing an immune response, a B-cell, cytotoxic T-cell, or helper T-cell may be used. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups VIII-IX and XI-XV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups VIII-IX and XI-XV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups VIII-IX and XI-XV.

The inventions of Group X and Groups IX and XI are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vaccine composition can be used in a materially different process such as for treating cancer or inhibiting the development of cancer.

The inventions of Group III and Group XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in a materially different process such as in an immunoassay for detecting a polypeptide.

The inventions of Group II and Groups XIII-XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein can be used in a materially different process such as inducing an immune system response in either a B-Cell, cytotoxic T-cell or helper T-cell.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search of the literature required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claims 36 ad 38, Groups VI-VIII, are generic to a plurality of disclosed patentably distinct species comprising the following cancers: prostate, testis, kidney, brain... colon and lung which differ at least in morphology and function such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any

claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER